UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 7, 2018

OFFICE OF CONGRESSIONAL
AND INTERGOVERNMENTAL RELATIONS

The Honorable John Shimkus
Chairman
Subcommittee on Environment
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Chairman Shimkus:

Enclosed please find the U.S. Environmental Protection Agency's responses to the Subcommittee's Questions for the Record following the September 6, 2018, hearing on "Perfluorinated Chemicals in the Environment: An Update on the Response to Contamination and Challenges Presented."

If you have further questions, please contact me or your staff may contact Matt Klasen in the EPA's Office of Congressional and Intergovernmental Relations at klasen.matthew@epa.gov or (202) 566-0780.

Sincerely,

Aaron Ringel
Deputy Associate Administrator

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CONGRESSIONAL
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The Honorable Paul Tonko
Ranking Member
Subcommittee on Environment
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Ranking Member Tonko:

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Enclosure

Post-Hearing Questions for the Record
Submitted to Peter C. Grevatt, Ph.D.
Office of Ground Water and Drinking Water
Office of Water
U.S. Environmental Protection Agency
House Committee on Energy and Commerce Subcommittee on Environment
Hearing on "Perfluorinated Chemicals in the Environment: An Update on the Response to Contamination and Challenges Presented"
September 6, 2018

The Honorable John Shimkus

1. Your testimony states that there are "many PFAS chemicals."

   a. What is the correct number?

   Approximately 1,220 PFAS are on the Toxic Substances Control Act (TSCA) Inventory, which is a list of chemical substances that are manufactured, processed, or imported in the United States for uses under TSCA. Of these, approximately 550 have been reported as having been in US commerce in the past 10 years. The OECD estimates that 4,730 PFAS-related compounds have been identified globally.

   b. Of the chemicals in the PFAS class -
      i. How many of them are well-understood?

      Few if any of the PFAS are "well understood." Data on human health effects are not available on the majority of PFAS. Even for those compounds for which some animal studies have been done, the studies do not cover all health effects. As such, many questions remain unanswered.

      Our scientific understanding of PFAS compounds stems almost entirely from studies on a select few. Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) have been manufactured the longest, are the most widespread in the environment, and are the most well-studied. The EPA has established health advisories for PFOA and PFOS, in drinking water and released two draft toxicity assessments (perfluorobutane sulfonate, PFBS and hexafluoropropylene oxide dimer acid and ammonium salt, GenX chemicals) in November 2018 for public review. The EPA is working to develop computational toxicity screening tools to better understand the many PFAS in commerce and the environment.

      ii. For how many is the Agency missing health effects data?

      Although the EPA does not have health information for the majority of PFAS, the Agency is working to move research forward to better understand how available epidemiological and toxicological data on PFAS (such as PFOA and PFOS) can be applied to inform our knowledge of other PFAS. For those PFAS that have been reviewed by the EPA's new chemicals program, the EPA has relied on available data on PFAS for which data already exist and/or have requested additional data be generated.

2. EPA has very robust authority under the reforms made to title I of the Toxic Substances Control Act to require the production of new information on a chemical substance. If there is so little known about PFAS health effects data, why isn't EPA using this authority to quickly fill these information gaps?

   The EPA has made it a priority to identify what data needs to be generated on what types of PFAS to better understand the impacts of PFAS. Once we know this, we will be better positioned to identify the appropriate TSCA authorities to obtain this data. Under Section 4 of TSCA, the EPA may require testing or development of information if such information is needed to evaluate a chemical. In addition, the EPA may, as appropriate and consistent with the requirements of TSCA, require testing under section 4 or reporting of information under Section 8 to prioritize and evaluate existing chemicals.

3. How similar are the chemicals in the PFAS class to each other - in other words, do they all act the same in the environment, do they all have the same effect on the human body?

   Based on differences in structure, not all PFAS will act the same in the environment or have the same effect on the human body, but some may have similar impacts. Due to their strong carbon-fluorine bonds, PFAS are very stable in the environment. Differences associated with chain length, chemical structure, and functional groups incorporated into individual PFAS have important implications for mobility within the environment and uptake, metabolism, clearance, and toxicity in the human body.

4. Your testimony mentions that "there is evidence that exposure to certain PFAS may lead to adverse health effects." This sounds scary, but you just mentioned that the majority of PFAS chemicals are not well understood.

   a. Is there a difference in certainty between "there is evidence" and "science demonstrates"?

      Evidence suggesting adverse health effects may happen is more speculative and less conclusive than "science demonstrates."

   b. What are the "certain PFAS" that "may"?

      The majority of research on the potential health risks associated with PFAS exposure is based on laboratory animal and human epidemiological studies of long-chain PFAS, such as PFOA and PFOS. Exposure to certain PFAS, such as PFOA and PFOS, above certain levels are suspected to cause adverse effects on human health based on results from animal studies and epidemiological studies of human populations. As NIH testified on September 26 before the Senate Committee on Homeland Security and Governmental Affairs' Subcommittee on Federal Spending Oversight and Emergency Management, our understanding of the health effects associated with PFAS and our ability to draw conclusions regarding the contribution of any specific PFAS to human disease is based on combined data from multiple studies investigating epidemiologic associations in human cohort studies, biological plausibility and pathways in animal studies, mechanistic effects seen in human tissues and cell culture systems, and rapid high-throughput screening. It is important to note that epidemiologic association studies cannot definitively find causation, and while animal studies are an important marker of scientific discovery, they are not perfect predictors of human effect. However, by combining and carefully

considering data from independent studies, we can begin to build an understanding of how PFAS chemicals impact human health.

Depending on the PFAS, potential adverse effects may include developmental effects to fetuses during pregnancy and to breastfed infants (e.g., low birth weight, accelerated puberty, skeletal variations), cancer (e.g., testicular, kidney), liver and kidney effects (e.g., tissue damage), immune effects (e.g., changes in antibody production and acquired immunity), thyroid effects, neurotoxicity, and other effects (e.g., in total serum cholesterol).

c. Are all PFAS toxic?

The EPA is working to gain an understanding of potential human health impacts of PFAS. Due to the similarities in the compounds to well-studied PFAS, such as PFOA and PFOS, it is anticipated that additional PFAS may be of concern to human health. Not all of the approximately 550 PFAS reported as having been in U.S. commerce in the past 10 years have been studied. The toxicity of PFAS is dependent on a number of factors which likely depend on existing body burden, the number of PFAS individuals are exposed to, the chemical identity of PFAS, the life stage and gender of the receptor, along with the duration of exposure. Toxicity alone is not sufficient to determine whether PFAS present risk: potential for exposure to people also needs to be estimated.

5. Your testimony talked about the health advisory level of 70 parts per trillion (ppt), individually or combined, for PFOA and PFOS. How low of a reading can existing monitors detect these contaminants?

The EPA laboratory that developed Method 537 (published September 2009) identified quantitation limits ("Lowest Concentration Minimum Reporting Levels" [LCMRL]) for PFOA and PFOS of 5.1 ppt (ng/L) and 6.5 ppt (ng/L), respectively. Laboratories have developed experience with PFAS analyses since Method 537 was published and some are now able to quantify at lower levels. In November 2018, the EPA updated Method 537 (537.1) to include an additional 4 PFAS and lowered the quantification limit for PFOA and PFOS to 0.82 ppt (ng/L) and 2.7 ppt (ng/L) respectively.

6. Today's hearing has raised questions about EPA being able to protect vulnerable subpopulations from adverse health effects.

a. To do that, wouldn't the Agency necessarily have to do aggregate and cumulative exposure analyses?

No, not necessarily. There are things that can be done to protect vulnerable subpopulations from adverse health effects without conducting aggregate and cumulative exposure analyses. Some examples include encouraging or requiring substitution of hazardous chemicals with safer alternatives or developing risk management guidance and exposure limits based on a toxicological reference value.

b. Does the Agency have an agreed upon protocol for doing aggregate exposure assessments?

The EPA does not have a single protocol for doing aggregate exposure assessments. Different program offices within the EPA are charged with implementing different environmental laws.

Each law has its own regulations and requirements in terms of the kind of assessments needed, which may require protocols to differ.

c. Does the Agency have an agreed upon protocol for doing cumulative exposure assessments?

The EPA does not have a single protocol for doing cumulative exposure assessments. Different program offices within the EPA are charged with implementing different environmental laws. Each law has its own regulations and requirements in terms of the kind of assessments needed, which may require protocols to differ.

7. For site remediation of PFAS,
   a. What are the available methods that may be deployed?

The following methods have been tested and shown to be effective at removing certain PFAS from groundwater:

- *Granular activated carbon*
- *Powdered activated carbon*
- *Anion exchange resin*
- *Reverse osmosis*
- *Nanofiltration*

In addition to contaminated groundwater, remediation of contaminated soil and other solids may be feasible through:

- *Incineration*
- *Land disposal in a lined, permitted landfill*
- *Solidification/stabilization*

Additional remediation technologies for soil and groundwater are under development and assessments by researchers may provide additional cleanup alternatives for PFAS contamination. Remediation effectiveness can vary based on the specific PFAS.

   b. What is the Federal government doing to ensure communities have sufficient information to assess the public health benefits against the cost for deploying these systems?

At EPA-led sites, the EPA provides information to communicate the hazards, exposures, risks and uncertainties associated with PFAS as information becomes available. At sites where the EPA is a support agency, the EPA collaborates with the lead organization to promote appropriate communication regarding PFAS. Further, the EPA provides information to communities through its PFAS website and social media. On a national level, the EPA is working to develop a PFAS Management Plan using information from the EPA's May 2018 PFAS National Leadership Summit, community engagements, and public comments submitted to the agency. The management plan will provide the EPA's approach on identifying and understanding PFAS, the agency's actions to address PFAS, and effective strategies for communicating with the public on PFAS.

8. For drinking water systems,

   a. What are the available remediation methods that communities may deploy to address PFAS contamination?

      Treatment options which have been tested and are known to address certain PFAS in drinking water include activated carbon (granular or powdered), ion exchange, and membrane separation (reverse osmosis, and nanofiltration). These remediation options may generate waste containing PFAS, which will need to be disposed of properly. More information can be found in the EPA's Drinking Water Treatability Database:
      https://oaspub.epa.gov/tdb/pages/general/home.do

   b. How effective are these?

      The effectiveness of these drinking water treatment methods will depend on multiple aspects of the treatment process including the properties of the specific PFAS compounds being remediated, properties of source water, treatment capabilities and operation of the system, as well as competing treatment priorities for other regulated contaminants. The following processes were found to be effective for the removal of certain PFAS:

      - *granular activated carbon (GAC) (up to > 98 percent)*
      - *membrane separation (up to > 99 percent)*
      - *ion exchange (up to > 99 percent).*

      These results cover the removal of specific PFAS including perfluorodecanoate (PFDA), perfluorononanoic acid (PFNA), perfluoroheptanoic acid (PFHxA), perfluorohexane sulfonic acid (PFHxS), perfluorobutanoic acid (PFBA), and PFBS.

      The following drinking water treatment techniques and the effectiveness of each are presented for PFOS:

      - *Granular activated carbon: highly effective for drinking water (at least 99% removal);*
      - *Powdered activated carbon: effective for drinking water (between 75% and 99% removal);*
      - *Anion exchange resin: effective for drinking water (between 75% and 99% removal);*
      - *Reverse osmosis: highly effective for drinking water (at least 99% removal);*
      - *Nanofiltration: highly effective for drinking water (at least 99% removal).*

      More information can be found in the EPA's Drinking Water Treatability Database:
      https://oaspub.epa.gov/tdb/pages/general/home.do

   c. Are there other technologies being examined to address potential drinking water contamination?

      Treatment using chlorine and advanced oxidation processes have been evaluated for their effectiveness at treating PFOS in drinking water but have not been found to be effective. The effectiveness of each treatment method will depend on the properties of the specific PFAS being remediated. The EPA continues to conduct research on additional technologies for addressing PFAS, working in collaboration with water utilities, universities, water treatment companies, and other federal agencies. As new information becomes available about effective technologies,

*it will be added to the EPA's Drinking Water Treatability Database (*https://oaspub.epa.gov/tdb/pages/general/home.do*)*

9. Please explain how EPA is addressing emerging contaminants, such as PFAS, with respect to environmental cleanups?

   The EPA is currently developing groundwater cleanup recommendations for PFOA and PFOS at contaminated sites.

10. When does EPA intend to have resolution on whether PFOA and PFOS are hazardous substances under Superfund?

    The EPA is beginning the necessary steps to evaluate the designation of PFOA and PFOS as "hazardous substances" through one of the available statutory mechanisms, including potentially the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) Section 102.

The Honorable Paul Tonko

1. National Management Plan

   a. What specific EPA actions are being considered as part of the National Management Plan?

      The EPA is using the information gained from the National Leadership Summit, community engagements and public input to develop its PFAS Management Plan. The EPA may include short-term implementation actions, and long-term regulatory and research approaches that the EPA designed to reduce the health risks associated with certain PFAS in the environment. Taken together, the plan is being designed to help the EPA to better assist states, tribes, and local communities to protect public health.

   b. Will the Plan include a decision on whether or not to designate PFOA and/or PFOS as a hazardous substance under CERCLA?

      Following the PFAS Summit in May, the EPA began an intensive effort to examine the statutory options that could be used if it determines it is appropriate to designate PFOA and PFOS as hazardous substances. Available statutes, including the Resource Conservation and Recovery Act (RCRA), TSCA, the Clean Water Act (CWA), the Clean Air Act (CAA), and CERCLA Section 102 are being considered, as well as the timing, benefits and challenges to pursue each option. The EPA has not used its authority under CERCLA Section 102(a) to designate a chemical as a hazardous substance directly under CERCLA. The EPA has concluded that any option to designate PFAS as a hazardous substance would require notice and comment rulemaking.

2. Dr. Grevatt, you mentioned building out capacity for labs to test for PFAS.

   a. How many labs in the United States are now capable of using Method 537 (or an EPA-approved method for testing for PFAS)?

*States generally certify/accredit laboratories that support drinking water compliance monitoring for regulated contaminants. The EPA is aware that some states also offer (and others plan to offer) programs for laboratories that wish to be certified/accredited to analyze drinking water for unregulated contaminants such as PFAS using Method 537. For example, the New Hampshire Department of Environmental Services lists 20 analytical labs capable of analyzing PFAS (https://www.des.nh.gov/organization/commissioner/documents/pfoa-testing-labs.pdf.) The EPA is also aware that the Department of Defense (DOD) manages a PFAS laboratory accreditation program that lists DOD accredited labs (*https://www.denix.osd.mil/edqw/accreditation/accreditedlabs/*).*

Any published list, however, is likely not inclusive of every laboratory in the U.S. capable of analyzing PFAS. Other federal or state agencies may have compiled their own lists of laboratories capable of providing analytical services for PFAS.

b. What is the approximate cost of testing for PFAS at one of these labs?

Using EPA method 537, typically, the fee is approximately $300 ± $50 per sample. The analytical cost will depend on multiple factors: current demand for the analysis (high demand and low lab capacity = higher quoted fee), how many PFAS targets are requested for monitoring, and how many samples a specific client will be sending to the lab (volume discounts typically apply).

c. While EPA is considering whether a regulatory determination should be made for PFOA and PFOS, are you also considering what financial or technical assistance options may be available for testing and treating the water of citizens relying upon private wells, which would not be bound by a MCL?

The EPA is currently investigating efficacy of commercially available point-of-use or point-of-entry applications. This work would inform private well owners of their risk management options. The EPA also provides technical assistance to laboratories analyzing drinking water samples on an as-needed basis.

The Honorable Scott H. Peters

1. Studies tracking PFOS in marine organisms and ocean waters, PFOS was added to the Stockholm Convention on Persistent Organic Pollutants in 2009, and we are not party to that Convention but is EPA doing anything to monitor coastal waters for these compounds and are you working with other countries to control the spread of these contaminants?

While it is true that the United States is not a Party to the Stockholm Convention on Persistent Organic Pollutants (POPs), it is a signatory to that Convention and is an active participant in its operation. To that end, the EPA does work with our international partners on emerging contaminant issues, including PFAS, through our observer status under the POPs Convention. The EPA's work on addressing such contaminants, however, is not limited to that forum. For example, the EPA monitors PFAS in fish in coastal waters via the Great Lakes Human Health Fish Fillet Tissue Study (fillet tissue only) and the Great Lakes Fish Monitoring and Surveillance Program (whole fish). Great Lakes work, in particular, is coordinated with Environment and Climate Change Canada, whenever possible.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CONGRESSIONAL
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The Honorable Gary C. Peters
Ranking Member
Subcommittee on Federal Spending Oversight
and Emergency Management
Committee on Homeland Security and
Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Ranking Member Peters:

Enclosed please find the U.S. Environmental Protection Agency's responses to the Subcommittee's Questions for the Record following the September 26, 2018, hearing on "The Federal Role in the Toxic PFAS Chemical Crisis."

If you have further questions, please contact me or your staff may contact Matt Klasen in the EPA's Office of Congressional and Intergovernmental Relations at klasen.matthew@epa.gov or (202) 566-0780.

Sincerely,

Troy M. Lyons
Associate Administrator

Enclosure

Post-Hearing Questions for the Record
Submitted to Peter C. Grevatt, Ph.D.
Office of Ground Water and Drinking Water
Office of Water
U.S. Environmental Protection Agency

Senate Committee on Homeland Security and Governmental Affairs
Subcommittee on Federal Spending Oversight and Emergency Management
"The Federal Role in the Toxic PFAS Chemical Crisis" – September 26, 2018

The Honorable Gary C. Peters

1. What steps is EPA taking to establish the methods for measuring PFAS in soil and groundwater? What is the expected timeframe for these methods to be established and agreed upon nationally?

The EPA validated and published its original method (Method 537) for monitoring 14 PFAS in drinking water (including drinking water obtained from groundwater sources) in 2009. This method was expanded in November 2018 (published as Method 537.1) and can now measure 18 different PFAS. The EPA is working to develop additional drinking water analytical methods for other PFAS as well as two different methods for quantifying 24 PFAS in surface water, groundwater, and wastewater matrices (non-drinking water) and solids (e.g., soil and sediment). The EPA anticipates completing these new methods in 2019. These new methods will include multi lab validations to document repeatability and will be added to the EPA's Hazardous Waste Test Methods SW-846. The EPA has developed and continues to conduct research to develop new analytical methods which can be used to measure a wide variety of PFAS in different media.

2. As recently as five years ago, EPA had to rely upon industry provided records to understand what PFAS chemicals were manufactured or utilized. The Agency's Significant New Use Rule authority provided by the recent TSCA reauthorization was intended to help the agency better understand what chemicals are being produced or used here in the United States. Can you elaborate on EPA's use of the "Significant New Use Rule" authority to potentially understand new uses of PFAS chemicals before they are commercialized? Specifically, will the Significant New Use Rule help EPA better understand the implications of PFAS chemicals as a class, or does EPA interpret the authority provided by Congress to be more narrowly tailored to assess the two specific chemicals, PFOA and PFOS?

The EPA has published several SNURs under TSCA to require manufacturers (including importers) and processors of some PFAS chemicals to notify the EPA at least 90 days before starting or resuming new uses of these chemicals. The EPA action prohibits new uses of PFAS chemicals until notice is submitted, EPA reviews, and makes a determination regarding unreasonable risk posed by the new use. The EPA is required to take action, as appropriate, to address any unreasonable risk. The SNURs apply to all PFAS chemicals included in the SNURs, not just PFOA and PFOS.

Relevant to understanding which PFAS chemicals on the TSCA Inventory are active in U.S. commerce, the EPA will soon be publishing an updated version of the TSCA Inventory that will include all substances designated as either active over the past 10 years or inactive per reporting under the TSCA Inventory Notification (Active/Inactive) framework rule.

The Honorable Margaret Wood Hassan

1. How many Americans are known or expected to have been exposed to PFAS in their drinking water? Is this estimate you provide for people on public water supplies or does it include people on private drinking water wells?

The EPA worked with states and public water systems (PWSs) to characterize the occurrence of six PFAS in the nation's drinking water served by public water systems (PWSs) by including six PFAS in the third Unregulated Contaminant Monitoring Rule (UCMR) under the Safe Drinking Water Act (SDWA) (UCMR does not sample private wells.). From 2013-2015, drinking water samples were collected and analyzed for six PFAS in nearly 5,000 PWSs across the nation, accounting for approximately 80 percent of the U.S. population served by PWSs (approximately 250 million people).

The EPA found 4.0 percent of PWSs (198 out of 4,920 systems) reported results for which one or more of the six PFAS (PFOA, PFOS, perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS), (perfluoroheptanoic acid) PFHpA, or perfluorobutane sulfonate (PFBS)) was measured at or above the minimum reporting limit during one or more sampling events at one or more sampling locations. The minimum reporting limit is lower than EPA's lifetime HA. The UCMR data are the best-available data on the frequency and level of occurrence of these PFAS in public water systems nationally, but they do not provide information on the occurrence in private wells.

2. How many Americans have been exposed to levels of PFOA and PFOS that exceed the EPA drinking water guideline?

To provide Americans, including the most sensitive populations, with a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water, the EPA has established the health advisory levels at 70 parts per trillion. When both PFOA and PFOS are found in drinking water, the combined concentrations of PFOA and PFOS should be compared with the 70 parts per trillion health advisory level. This health advisory level offers a margin of protection for all Americans throughout their life from adverse health effects resulting from exposure to PFOA and PFOS in drinking water. The health advisory value is derived based upon peer-reviewed studies of the effects of PFOA and PFOS on laboratory animals (rodents) demonstrating the potential for developmental effects. Under the third Unregulated Contaminant Monitoring Rule, discussed in the response to the preceding question, the EPA found that 1.3 percent of the participating PWSs (63 out of 4,920 PWSs reporting) had at least one sample that measured PFOA and/or PFOS at concentrations greater than 70 ppt. The EPA believes the UCMR3 data provide the best-available data regarding the frequency and level of contaminant occurrence in public water systems. However, the EPA has not developed estimates of the national population served by public water systems at levels greater than the Health Advisory. The EPA also does not have nationally representative data on PFOA and PFOS levels associated with private wells.

3. When did the EPA begin developing its drinking water guideline for PFOA and PFOS?

The EPA initiated its health assessments for PFOA and PFOS in 2009. Draft Health Effects Support Documents for PFOS and PFOA were released for public comment in February 2014. The final Health Effects Support Documents and Lifetime Health Advisories were published in May 2016. See Health Effects Support Documents and Health Advisories for PFOA and PFOS at https://www.epa.gov/ground-water-and-drinking-water/supporting-documents-drinking-water-health-advisories-pfoa-and-pfos.

4. When were the guidelines publicly available?

The non-regulatory Lifetime Health Advisory levels for the sum of PFOA and PFOS concentrations was released in May 2016.

5. When were the data documenting the presence of PFAS under the Safe Drinking Water Act's Unregulated Contaminant Monitoring Rule analyzed? When were they made publicly available?

The UCMR 3 data were collected from 2013-2016 and were analyzed thereafter. The EPA published UCMR 3 data approximately quarterly throughout the monitoring program following review. The data summary was published in January 2017, available at https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf. The EPA continues to assess the data.

6. How many years have passed since the EPA has known that PFAS – including PFOA and PFOS are present in public drinking water supplies?

The EPA conducted a nationwide survey of drinking water systems under the third Unregulated Contaminant Monitoring Rule, which began sampling drinking water in 2013.

7. What is the difference between a guideline and a standard?

Standards, such as maximum contaminant levels set under the Safe Drinking Water Act (SDWA), are enforceable requirements that drinking water systems must follow. Guidelines, such as the EPA's Health Advisories, are non-enforceable and non-regulatory. They are intended to provide technical information to state agencies and other public health officials on potential health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. The health advisory level for PFOA and PFOS were calculated to offer a margin of protection for fetuses during pregnancy and breastfed infants as well as for all Americans throughout their life.

8. If an EPA standard is developed, are all states required to meet the standard?

Yes, when the EPA establishes a standard under SDWA, states, territories, and tribes are required to meet that standard. In addition, states, territories, and tribes that have been delegated primary enforcement responsibility (primacy) must adopt standards that are no less stringent than the EPA's regulations.

9. If an EPA standard is developed, are DoD facilities required to meet the very same standard(s)? Why or why not?

DoD facilities that are public water systems and are located within the United States (including territories) are required to meet SDWA requirements, including meeting any applicable drinking water standards.

10. The Centers for Disease Control Agency for Toxic Substances and Disease Registry released its Toxicity Profile for PFAS this summer. The ATSDR guidelines for PFOA and PFOS are almost 10 times less than the EPA drinking water guidelines. Why is this?

On June 20, 2018, ATSDR released a draft Toxicological Profile for perfluoroalkyls for public comment. This document includes Minimal Risk Levels (MRLs) for four PFAS – Perfluorooctanoic acid (PFOA), Perfluorooctane sulfonic acid (PFOS), Perfluorononanoic acid (PFNA), and Perfluorohexane sulfonic acid (PFHxS). ATSDR released the draft Toxicological Profile after working collaboratively with the EPA, the Food and Drug Administration, the National Institutes of Health (including the National Institute of Environmental Health Sciences), the National Toxicology Program, the U.S. Geological Survey, and the Department of Defense (DoD).

ATSDR's MRLs and the EPA's Health Advisories (HAs) are two different tools that are used in different situations. Drinking Water HAs provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. They are a concentration in drinking water that is not expected to cause any adverse human health effects over an exposure period (e.g. 1-day, 10-day, lifetime). The EPA's health advisories are non-enforceable and non-regulatory and provide technical information to states agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. Drinking water HAs are calculated incorporating toxicity (i.e., reference doses or RfDs) and exposure parameters (i.e., drinking water intake, body weight, and other potential sources of exposure).

ATSDR's MRLs are toxicity values that are intended to be used to help public health professionals determine areas and populations potentially at risk for health effects from exposure to a particular chemical. MRLs do not take into account specific exposures like a drinking water HA. MRLs are intended only to serve as a screening tool to help public health professionals decide where to look more closely; they are not intended to indicate a maximum safe exposure level. Drinking water HAs provide non-enforceable technical guidance to state agencies and other public health officials who have the primary responsibility for overseeing drinking water systems. The health advisory level for PFOA and PFOS offer a margin of protection for fetuses during pregnancy and breastfed infants as well as for all Americans throughout their life.

ATSDR's MRLs for PFOA and PFOS differ by an order of magnitude from the toxicity values that were derived by EPA in development of the drinking water HAs due to differences in the critical study selected (PFOA) and uncertainty factors applied (PFOS). Other health agencies may issue different values based on their own analyses, including more stringent values that may reflect more conservative assumptions. The EPA supports the efforts of other federal partners, including ATSDR, to develop information related to PFAS. The EPA continues to take concrete steps, in cooperation with our federal and state partners, to address PFAS and ensure all Americans have access to clean and safe drinking water. The EPA will continue to carefully review the draft ATSDR Toxicological Profile and will consider any information that may inform our approach to PFOA, PFOS, and other PFAS.

11. In your opinion, do the EPA guidelines meaningfully reduce risk to human health?

The EPA's health advisories are non-enforceable and non-regulatory and provide technical information to states agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. The EPA's health advisory level for PFOA and PFOS offers a margin of protection for all Americans throughout their life from adverse health effects resulting from exposure to PFOA and PFOS in drinking water.

12. Based on the scientific evidence, do you think that the EPA guidelines set for PFOA and PFOS are health protective? Are they specifically protecting infants who are bottle fed with water from their contaminated home source or those who are breast fed where moms are drinking contaminated water?

Based on the available scientific evidence, the EPA believes the Health Advisory levels for PFOA and PFOS are protective of human health. These levels include margins of safety and consider sensitive individuals, including fetuses during pregnancy and breastfed and bottle-fed infants.

13. Do you think that the EPA drinking water guidelines should be developed for the suite of chemicals measured in the UCMR and not just for PFOA and PFOS?

The EPA will work with our federal, state, tribal, and local partners on response actions and research into the health and environmental impacts of these PFAS substances. The EPA is continuing to work to develop a PFAS Management Plan that will outline the Agency's approach to addressing the PFAS challenge.

14. The last drinking water standard EPA developed was way back in the 1990s and in fact was only a lowering of the arsenic standard. Does EPA have the person power and technical abilities to develop PFAS federal drinking water standards?

The EPA's technical experts are dedicated to assuring that National Primary Drinking Water regulations assure public health protection in accordance with SDWA. The EPA has promulgated a number of drinking water regulations that strengthen public health protection since the 1996 amendments to SDWA. These regulations, including those designed to reduce risks from arsenic, disinfection byproducts, radionuclides, and microbial pathogens that can come from a variety of sources including surface water, ground water and airplane drinking water systems, were developed in consultation with states, the EPA's National Drinking Water Advisory Council, the Science Advisory Board and/or other interested stakeholders.

Additionally, SDWA requires the EPA to regularly assess and evaluate unregulated contaminants. The EPA has published four Contaminant Candidate Lists, promulgated and implemented four Unregulated Contaminant Monitoring Regulations, and made regulatory determinations for 25 contaminants in accordance with SDWA. The EPA must also review each national primary drinking water regulation at least once every six years and revise them, if appropriate. As part of the "Six-Year Review," the EPA evaluates any newly available data, information and technologies to determine if any regulatory revisions are needed. Revisions must maintain or strengthen public health protection. The EPA's third Six-Year Review evaluated thousands of peer reviewed studies and millions of data points from drinking water treatment systems and was published in January 2017. The results of that review identified rules the EPA can evaluate whether to modify to strengthen public health protection in future years. This review ensures that existing rules are offering the maximum public health benefit feasible.

For more information about the timelines under which drinking water regulations were promulgated, please see https://www.epa.gov/sites/production/files/2015-10/documents/dw_regulation_timeline.pdf.

15. If so, how long would it take to develop and promulgate a standard?

Under the SDWA-mandated regulatory determination process, the EPA must consider three criteria when making a determination to regulate a contaminant:

- *The contaminant may have an adverse effect on the health of persons*
- *The contaminant is known to occur or there is a high chance that the contaminant will occur in public water systems often enough and at levels of public health concern*
- *In the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems*

When making a determination, the EPA first publishes a preliminary regulatory determination in the Federal Register (FR) and provides an opportunity for public comment. After review and consideration of public comments, the EPA would publish a final FR notice with the regulatory determination decisions. If the EPA were to make a final determination to regulate a particular contaminant, the Agency would start the rulemaking process to establish the National Primary Drinking Water Regulation (NPDWR). The SDWA requires that the EPA propose a regulation within 24 months of making a determination to regulate a contaminant, and to promulgate a regulation within 18 months of proposal (with an option of extending this time frame by up to 9 months).

The EPA believes the time frame allotted for promulgating drinking water regulations is appropriate because of the steps required under SDWA. As part of this process, the EPA reviews health effects data that the Agency would use to set a maximum contaminant level goal (MCLG). The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. MCLGs are non-enforceable public health goals. Once the MCLG is determined, the EPA sets an enforceable standard, which is established as either a maximum contaminant level (MCL) or a "treatment technique." The MCL is the maximum allowed level of a contaminant in water which is delivered to any user of a public water system.

The EPA must consider feasibility of treatment and monitoring when selecting an enforceable limit. SDWA also requires the EPA to prepare a health risk reduction and cost analysis in support of any NPDWR. The EPA must analyze the quantifiable and non-quantifiable costs and benefits that are likely to occur as the result of compliance with the proposed standard. The EPA must determine if the benefits of the regulation justify or do not justify the costs. Finally, the EPA must consult with experts and stakeholders including the National Drinking Water Advisory Council and the Science Advisory Board. These analyses and consultations can take significant time but assure that state and local resources are focused upon the most important public health priorities.

16. How many people's health will be harmed in the time it takes to develop a national standard?

Protecting public health is the EPA's primary mission. The EPA will continue to carry out the requirements of SDWA in order to ensure that citizens across the United States continue to have safe and clean drinking water.

17. When we know that very small amounts of PFAS can negatively affect health, why is EPA treating results below the UCMR minimum reporting levels (MRLs) [20 ppt PFOA; 40 ppt PFOS] as "zero"? Are they zero or are they levels that we need to be concerned about?

The HA for PFOS and PFOA is 70 ppt.

The EPA set the MRLs for UCMR 3 after looking at the performance of multiple laboratories that conducted studies to determine how low they could reliably measure the concentration of contaminants. To establish these levels, the EPA vetted those MRLs through the notice-and-comment UCMR 3 rulemaking. The EPA set the UCMR 3 MRLs such that we would have high confidence that a capable analyst/laboratory could meet those levels and report numeric results. Per the rule, no results below that level were reported.

The EPA is aware that some laboratories are able to reliably measure PFAS in drinking water at lower levels. The EPA advises states or others who may be leading the collection of PFAS data since the UCMR to consider establishing lower MRLs to meet any project-specific data quality objectives, provided the laboratories can demonstrate acceptable performance at the specified concentrations of interest.

18. The PFASs have been in commerce for tens of years. Can the Lautenberg Amendment to the Toxics Substances Control Act be used to require pre-market testing of all of the PFASs? What is preventing this from happening?

The EPA's new chemicals review program reviews all new PFAS chemicals intended for TSCA uses before they are allowed to commercialize and must make a determination regarding unreasonable risk of injury to health or the environment. The EPA reviews new substances to identify whether the range of toxicity, fate, and bioaccumulation issues that have caused past concerns with long-chain PFAS may be present, as well as any concerns that may be raised by new chemistries, in order to make an affirmative safety determination. In addition to being able to require testing under TSCA section 5(e), the EPA will also restrict uses pending development of additional information related to the chemical (e.g. testing), where appropriate. Whether and what type of testing may be necessary depends on a number of factors such as the specific uses of the new chemical, and the similarities or differences of the new chemical relative to other PFAS chemicals Many of the PFAS on the active TSCA inventory have been through the new chemical review described above, PFAS that were in use prior to the enactment of TSCA were not subject to such a review. Approximately 200 of the PFAS that have been through EPA's new chemicals program have an associated consent order. Most of those orders contain a requirement for testing if certain conditions are met. Of these, approximately 140 have commenced production.

19. Filtration is the currently feasible technology to remove PFAS from water. The filters that contain the PFAS are then disposed of. Where are they disposed of? Are these toxic? Does this mean that PFAS should be listed as Superfund chemicals and disposed of in hazardous waste facilities?

Currently available methods for removing certain PFAS from drinking water include granular or powdered activated carbon, anion exchange, or high-pressure membrane separation techniques including reverse osmosis or nanofiltration. These methods may generate PFAS-contaminated waste, which should be managed consistent with state, tribal, and local requirements and in a manner that will minimize the potential for environmental releases.

The Resource Conservation and Recovery Act (RCRA) regulates hazardous waste disposal. The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, aka Superfund) regulates the cleanup of hazardous substances released to the environment. All chemicals designated as RCRA hazardous waste are CERCLA hazardous substances, though not all chemicals designated as CERCLA hazardous substances are RCRA hazardous waste. The EPA is currently evaluating all statutory mechanisms available to address PFOA and PFOS.

20. PFASs are measured in waste water and in sewage sludge. Does this mean that PFASs are now in our rivers, streams and lakes? Are our fish contaminated? If yes, why is EPA not regulating discharge to waterways?

PFAS are very persistent and mobile in environmental media, including wastewater and sludge. Some evidence shows that certain PFAS have been accumulating in the environment and in wildlife (including fish). The EPA and states regulate discharges of pollutants to Waters of the United States under the National Pollution Discharge Elimination System. The EPA and states are evaluating approaches to ensure that PFAS discharges to the environment are minimized.

21. What is EPA's plan to further engage with the community in NH and get direct input from Granite Staters about PFAS contamination in their waters?

The EPA held a community engagement meeting in Exeter, NH in June 2018. The EPA received input from community members at this meeting as well as through a public docket, which closed on September 28, 2018. The EPA is continuing to work to develop a PFAS Management Plan that will outline the Agency's approach to addressing the PFAS challenge. The Agency is working to release the plan as soon as possible.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 20 2018

OFFICE OF CONGRESSIONAL
AND INTERGOVERNMENTAL RELATIONS

The Honorable Rand Paul
Chairman
Subcommittee on Federal Spending Oversight
and Emergency Management
Committee on Homeland Security and
Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Chairman Paul:

Enclosed please find the U.S. Environmental Protection Agency's responses to the Subcommittee's Questions for the Record following the September 26, 2018, hearing on "The Federal Role in the Toxic PFAS Chemical Crisis."

If you have further questions, please contact me or your staff may contact Matt Klasen in the EPA's Office of Congressional and Intergovernmental Relations at klasen.matthew@epa.gov or (202) 566-0780.

Sincerely,

Troy M. Lyons
Associate Administrator

Enclosure